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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,836

04/26/2005

Armin Breitenbach

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EXAMINER

CHO, JENNIFER Y

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

04/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,836	<b>Applicant(s)</b> BREITENBACH ET AL.	
	<b>Examiner</b> JENNIFER Y. CHO	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 35-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **Detailed Action**

Receipt is acknowledged of the Response filed 11/30/2007.

Claims 35-39 are considered to be the elected invention. Claims 1-34 and 40-69 have been cancelled.

### **Claim Rejections – 35 USC 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35-39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Claus et al. (WO 99/58478) and Arne et al. (WO 94/11337). For reasons, see previous office action and responses stated herein.

### **Response to Arguments**

Applicant's arguments have been considered but are not persuasive for the following reasons:

The Examiner acknowledges Applicant's argument that Arne's disclosure only refers to optical purity rather than the purity as described in Applicant's claims, thus Arne's disclosure is not relevant.

The Examiner agrees that Arne's disclosure refers to optical purity. However, the Examiner takes the position that since Arne et al. is separating a mixture of optical isomers (page 6, lines 24-28), the optical purity as disclosed, is equivalent or closely similar to the isolated purity of the compounds (page 11, line 21). Furthermore, optimization of the purity of the final product is standard procedure in organic synthesis. One of ordinary skill in the art would be motivated to optimize the purity of the isolated product, lowering the salt content to less than 10% by weight, through routine and normal experimentation, with the reasonable expectation that a decrease in salt impurities would decrease side-effects and undesirable pharmacokinetic properties.

The Examiner acknowledges Applicant's argument that Arne et al. uses chromatography only to assess optical purity, not to obtain a compound in optically pure form.

The Examiner contends that Arne et al. does teach the separation of a mixture of optical isomers by chromatographic separation on chiral columns (page 6, line 24-28).

The Examiner acknowledges Applicant's argument that Arne et al. does not teach the claimed compounds in highly pure base form.

The Examiner contends that Arne et al. does teach that the free base form can be formed (page 6, line 37). In addition, Claus et al. also teaches both the free base and the salt form (page 35, third paragraph, first two lines).

The Examiner acknowledges Applicant's argument that the prior art teaches away from the free base form and preferential formation of the claimed compounds as

stable salts. Also acknowledged is the argument that the prior art teaches the free bases of the claimed compounds should be avoided in favor of the salts.

Again, the Examiner points out that Arne et al. teaches both the free base and the salt form (page 6, line 37). In addition, Claus et al. also teaches both the free base and the salt form (page 35, third paragraph, first two lines). Neither reference states that the free base form is undesirable.

The Examiner acknowledges Applicant's argument that the compounds show unexpected, superior results compared to the closest prior art compounds.

However, the Examiner does not consider Applicant's comparison to be with the closest prior art. Arne et al. teaches the hydrochloride salt form (page 11, lines 22-23). Applicant instead has shown a comparison with the fumarate salt form.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to modify the process parameters for chromatographic separation as taught by Arne et al. to obtain Claus et al.'s highly pure free base compound, with a salt content of less than 10% by weight. The expected result would be the efficient production of the free base of 3,3-diphenylpropylamino monoesters for the pharmaceutical industry.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Y. Cho whose telephone number is (571) 272 6246. The examiner can normally be reached on 9 AM - 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272 0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Cho  
Patent Examiner  
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Primary Examiner  
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